

1 UNITED STATES DISTRICT COURT
2 FOR THE EASTERN DISTRICT OF NEW YORK

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4 IN RE: PROPECIA : Master File No.
(FINASTERIDE) PRODUCTS : 1:12-md-02331-BMC-PK
LIABILITY LITIGATION :

5 _____ : MDL No. 2331

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6 This Document Relates to: : Honorable Brian M.
: Cogan

7 ALL CASES :
: Magistrate Judge
8 : Judge Peggy Kuo

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10 May 19, 2016

11 Confidential - Subject to Protective Order

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13 Oral sworn videotape deposition of
14 CHARLOTTE B. MERRITT, taken at the Short Hills
15 Hilton, John F. Kennedy Parkway, Short Hills, New
16 Jersey, 08078, before Patricia R. Frank,
17 Certified Court Reporter and Notary Public of the
18 State of New Jersey, commencing at 9:31 a.m., on
19 the above date.

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21
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1 let's look to the next label.

2 (Letter from Dr. Wilkin to Dr. Rozycki
3 and attached 2002 Propecia label marked Exhibit No.
4 210 for identification.)

5 BY MR. FISHER:

6 Q. This is a label from 2002, Exhibit 210.
7 When you're ready, if you turn to the adverse event
8 section -- adverse reaction section in this exhibit,
9 please? It's on page 11.

10 A. Okay.

11 Q. You're there on page 11, adverse
12 reactions?

13 A. Yes.

14 Q. And you see that here it's still just
15 limited to the 12-month data, right?

16 MR. HUDSON: Objection.

17 Q. It begins, "In controlled clinical trials
18 for Propecia of 12-month duration" -- and goes on,
19 right?

20 MR. HUDSON: Objection.

21 THE WITNESS: It mentions the fifth year
22 of treatment at the end of that paragraph.

23 Q. I'm going to come to that. That's right.
24 I'm going to come to that in a moment.

25 At the beginning it says, "In controlled

1 clinical trials for Propecia of 12 months" -- and it
2 reports the findings, right?

3 A. It reports the 12-month incidences, yes.

4 Q. And if you drop down to the second to
5 last paragraph -- second to last sentence in that
6 paragraph, it states, "Resolution occurred in men
7 who discontinued therapy."

8 Do you see that?

9 A. Yes.

10 Q. So the word "all" has been removed in
11 this label.

12 A. Yes, it has.

13 Q. Why was that?

14 A. Well, as you saw, there were some men in
15 whom after some period of time the AEs did not
16 resolve so this is -- so the word "all" was no
17 longer factual as relates to the longer term data
18 beyond the initial period of the trial.

19 Q. The sentence has also been changed to
20 take out "58 percent" and replace it with the word
21 "most." Do you see that?

22 A. Yes.

23 Q. And you would agree with me that the only
24 change that reflects the fact that there were in
25 fact men who had -- who did not have resolution upon

1 discontinuation, the only thing that reflects that
2 here is the taking out of the word "all," right?

3 MR. HUDSON: Objection. Go ahead.

4 Q. It doesn't also say there were men who
5 did not experience resolution upon discontinuation,
6 right?

7 A. No, it doesn't say that.

8 MR. HUDSON: Objection.

9 Q. And then as you point out, in the last
10 sentence that's been -- the new sentence there, it
11 says, "The incidence of each of the above side
12 effects decreased to less than or equal to 0.3
13 percent by the fifth year of treatment with
14 Propecia," right?

15 A. Yes.

16 Q. Okay. So that's a reference to the fifth
17 year, but there's no reference anywhere else to
18 years two, three or four, right?

19 A. No, there's not.

20 Q. Well, isn't this precisely what
21 Dr. Kaufman said in his 2000 e-mail was deceptive,
22 to simply report on the results in the fifth year of
23 the study and not --

24 A. It's not --

25 MR. HUDSON: Objection.

1 Q. I'm going to show you Exhibit 218. Do
2 you recognize this document, 218, a standby
3 statement, Q & A Merck statement in response to the
4 EMEA's recommended label update of Propecia?

5 A. Not specifically, no.

6 Q. Okay. Well, I can show you a document
7 that you are on that shows that you were involved in
8 editing of this. Do you need to see that to --

9 A. No, no, no. It was part of my
10 responsibility to review these types of things. I
11 just meant that I don't have any -- I don't have a
12 specific recollection of this one in particular.

13 Q. So you don't have any doubt that you were
14 involved in the editing --

15 A. No.

16 Q. -- and preparation of this document,
17 right?

18 A. I was involved in the review of it and
19 perhaps in drafting some of the responses.

20 Q. So this is a -- as I stated, it's a Merck
21 statement in response to the EMEA's recommended
22 label update, March 17, 2009. And it says,
23 "Communication Issue. We may receive questions from
24 media about the post-marketing reports of
25 persistence of erectile dysfunction following

1 discontinuation of Propecia and its severity and
2 frequency."

3 Do you see that?

4 A. Um-hum.

5 Q. And the standby statement includes in the
6 middle paragraph there the following statement: "In
7 the Phase 3 clinical trials for Propecia, resolution
8 of erectile dysfunction occurred in men who
9 discontinued therapy because of this side effect."

10 Do you see that?

11 A. Yes.

12 Q. And we talked about that before lunch,
13 about the fact that between the 2001 and 2002
14 label -- labels the word "all" was removed before
15 the word "men" there, right?

16 A. Correct.

17 Q. Because there were cases in the clinical
18 trials of men who discontinued therapy and did not
19 have resolution of the adverse event, right?

20 A. Yes, that's been established.

21 Q. On the next page, Ms. Merritt, there is
22 the Q and A. Do you see that?

23 A. Yes.

24 Q. And it notes that the -- in the second
25 question, that the labeling change is currently